

29. (New) The anaesthetic controller as defined in claim 17 including means (19) for generating a patient passive target signal ( $CNT_{MAN}$ ) of the active substance concentration, means (20) for generating a patient dependent target signal ( $CNT_{BIS}$ ) of the active substance concentration, and means (18) selectively responsive to said two last-mentioned means (19, 20) for transferring the desired value of the active substance concentration ( $CN_{desired}$ ) to effect desired rate (R) of supply of the active substance to the patient's body.

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### **Remarks**

After careful consideration of the outstanding Office Action, this application has been amended accordingly, and favorable reconsideration on the merits thereof is at this time respectfully requested.

Before considering the rejections of record, it is brought to the Examiner's attention that the undersigned has forwarded herewith a Letter to the Draftsperson requesting changes to the drawing, absent the addition of any new matter.

The changes include the addition of  $CN_{actual}$  and  $CN_{desired}$  to correspond the drawing to the specification and the claims.

The position of reference character 18 has been changed.

The vertical lines extending from the input means 19 and the input device 27 have been shifted to the right and joined to the obviously associated horizontal lines to correctly define the borders of the respective control portion 16 and the control portion 20. As originally presented, the

vertical lines last-mentioned appeared to be conductors, and obviously such is not the case.

Finally, the control line 25 is shown disconnected or crossing and not connected to the line between the components 11, 13, as is obvious from a reading of the specification.

Assuming the latter changes are acceptable to the Examiner, a formal drawing corresponding to the red-line drawing has also been filed herewith (attached to the Letter to Draftsperson) and the entry of the new formal drawing into the application is respectfully requested.

The claims originally of record have been cancelled, and the newly presented claims are each believed to be in complete compliance with the second paragraph of 35 U.S.C. § 112. Accordingly, the rejection predicated upon the latter paragraph and section of Title 35 is considered inapplicable to the newly presented claims.

At page 4, paragraph 18 of the outstanding Office Action, the Examiner rejected claims 1 through 6 and 8 "under 35 U.S.C. 102(b) as being anticipated by US 5,094,235 to Westenskow et al." The latter patent neither anticipates (35 U.S.C. § 102(b)) nor renders obvious (35 U.S.C. § 103(a)) independent claim 9. However, before considering claim 9, the Examiner's attention is directed to page 12 of the specification which fairly explains applicants' invention at the first full paragraph thereof. Quite simplistically, in order to first measure the current active substance concentration of the anaesthetic in the patient's body, the model computing means (10) is fed and analyzes previous supplies of the active substance of the anesthetic supplied to the patient's body and utilizes the latter through the patient model (11) to calculate the current actual value of the active

value concentration ( $CN_{\text{ACTUAL}}$ ) in the patient's body. Reference is specifically made to page 4, lines 4 through 7 of the specification. Claim 9 defines the latter invention by calling for the model computing means (10) for calculating actual current value of the current active substance concentration ( $CN_{\text{actual}}$ ) in a patient's body (14) on the basis of a patient model (11). Most importantly, the calculating is defined as being accomplished through the utilization of "former values (R) of the active substance previously supplied to the patient's body." Finally, the last limitation recites "control means (16) for changing the rate (R) of supply of the active substance supplied to the patient's body as a function of the actual current value ( $CN_{\text{actual}}$ ) of the current active substance concentration ( $CN_{\text{actual}}$ ) such that the present active substance concentration ( $CN_{\text{actual}}$ ) is controlled to attain a target value ( $CN_{\text{desired}}$ )."

At page 4, paragraph 19, the Examiner describes the Westenskow et al. teaching and states "a model computing portion 301 calculating a current value of the present active substance concentration in the patient's body on the basis of a patient model and taking into consideration former values of the active substance supply." With due respect, nothing in the Westenskow et al. patent, including the specific portions thereof alluded to by the Examiner, support the Examiner's latter-quoted statement. More specifically, nothing in the Westenskow et al. patent teaches anything with respect to analyzing, determining or calculating any value and specifically the present active substance concentration "**in the patient's body**." The latter is not the active substance concentration delivered to the patient but it is in fact the active substance concentration "**in the patient's body**." This concentration in the patient's body cannot be easily measured. However,

the patient model 11 considers time dependent reactions of the patient's body on the delivery of the amounts of the active substance as is inputted into the patient over a certain amount of time and the latter results in the calculated value ( $CN_{\text{actual}}$ ) which is fed to the concentration controller (17). The latter compares the active substance concentration **in the patient's body** ( $CN_{\text{actual}}$ ) with the desired value ( $CN_{\text{desired}}$ ) to effect desired infusion.

Turning to the Westenskow et al. patent, there is nothing in column 2, lines 29 through 48 which has any bearing on the subject matter just discussed with respect to claim 9. As is perhaps best expressed at page 2, between lines 15 through 17 of applicants' specification - "The patient model thus delivers, on the basis of the preceding active substance rates and supply periods, information on the present active substance concentration in the patient's body." Through the "predicting algorithm" of the patient model (11), the preceding active substance rates and supply periods are "used as actual value for control purposes" (applicants' specification, lines 22 through 23). Nothing comparable to the latter is found at column 2, lines 29 through 48 of the Westenskow et al. patent.

Column 7, line 14 through column 8, line 14 of the patent, which the Examiner has also referred to, evidences the absence of that which is disclosed, emphasized and claimed by applicants in claim 9. The so-called "model computing portion 301" of Westenskow et al. is a "logic component" by which the "anaesthetic agent concentration desired value 814" is compared "with the actual value measured by the anesthetic agent sensor 106." At column 7, between lines 19 and 22, there is specific reference to a signal line 823 for conducting "the actual value and the desired value 814 of the anesthetic agent concentration" to a limit value switch 312. The

anesthetic agent sensor 106 is illustrated in the right-side of Figure 1 in the "BREATHING CIRCUIT," and at column 5, lines 26 through 30 the Examiner will readily observe that the anesthetic agent sensor A (106) is located "at the expiratory end" of the breathing circuit which obviously measures the concentration of the anesthetic agent **within the breathing gas**, not that **"within the patient's body,"** as claimed. The so-called logic component 301 is simply a comparator which compares (subtraction) comprises the desired value 814 with the actual value "measured by the anesthetic agent sensor 106" in the breathing circuit 1 and, depending upon the "different signal" therebetween, the anesthetic agent is either "metered into the breathing circuit 1 in a quantity increased by a multiple of 10" or is not. (See column 7, lines 31 through 36.)

The Examiner states that the alleged patient model of Westenskow et al. functions by "taking into consideration former valuess of the active substance supply." The latter is untrue, as is evidenced by the varied portions of the patent cited by the Examiner relative to column 7. At any one time only one value is considered and the one value is compared with a desired value. Nowhere in this patent are "former valuess of the active substance supply" taken into consideration.

The Examiner need but refer to column 8, beginning at line 46 of the Westenskow et al. patent which describes Figure 2 and curves A, B and C. "The curve A indicates the concentration in the breathing circuit with this concentration being measured by the anesthetic agent sensor 106." The latter curve does not reflect the present active substance concentration in the patient's body, nor do curves B and C.

Should there be any questions in the Examiner's mind as to the Westenskow et al. teaching, he need but read claim 1, column 11, lines 48 through 50 reciting:

an anesthetic agent sensor for measuring the anesthetic agent actual value present in said breathing circuit.

The scope and content of the Westenskow et al. patent "as a whole" or in its entirety (Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966)) is totally silent as to calculating the actual current value of the current active substance concentration ((CN<sub>actual</sub>) "in a patient's body," as recited in claim 9 and doing so "on the basis of a patient model (11) by utilizing former values (R) of the active substance previously supplied to the patient's body." The undersigned has quoted verbatim from claim 9 and it is emphasized that the calculating of the recited computing means (10) not only relates to "in a patient's body," but the former values (R) are values of "the active substance" of the anesthetic and such as was "previously supplied."

Considering the entirety of the subject matter recited in claim 9 following "computing means (10) for calculating," etc., the Examiner must either find in the Westenskow et al. patent the subject matter claimed or the equivalent thereof. The Examiner has found neither and the Westenskow et al. teaching is contradictory to the Examiner's interpretation thereof.

Unless the Examiner can point to some specific language in the Westenskow et al. patent which anticipates or renders obvious the subject matter of claim 9, the formal allowance of claim 9 and each of the claims depending directly or indirectly therefrom is considered proper and would be most appreciated.

The undersigned has made a *bonafide* effort to place this application in condition for allowance and urges the allowance of all of the claims of record. In the event the Examiner considers proceeding forward other than by way of a former Notice of Allowance, he is requested to telephone the undersigned in order that a personal interview can be arranged by way of which the undersigned would be most pleased to discuss any portion of the Westenskow et al. patent, particularly any portion thereof which the Examiner feels is in any manner pertinent to the present invention. Absent a phone call from the Examiner to arrange such an interview, the formal allowance of this application is again respectfully requested.

Respectfully submitted,

DILLER, RAMIK & WIGHT

By: 

Vincent L. Ramik, Reg. No. 20,663

7345 McWhorter Place  
Suite 101  
Annandale, VA 22003

e-mail: [DRWPATENTLAW@AOL.COM](mailto:DRWPATENTLAW@AOL.COM)

Attachment: Letter to Draftsperson w/2 sheets drawings